



# Workshop on Vendor Oversight

## Procurement and Auditing Requirements

Compliance with Appendix B to 10 CFR Part 50  
and 10 CFR Part 21 When Procuring ASME  
Section III Components



Yamir Diaz-Castillo

Quality Assurance and Vendor Inspection Branch  
Office of Nuclear Reactor Regulation



# Agenda

2

- ☐ Background
- ☐ Regulations
- ☐ Procurement Requirements
- ☐ Auditing Requirements
- ☐ Summary
- ☐ Questions



# Background

3

- ❑ NRC's recognition of ASME's accreditation program is documented in Information Notice (IN) 86-21, "Recognition of American Society of Mechanical Engineers Accreditation Program For N Stamp Holders," and its supplements March 31, 1986, December 4, 1986, and April 16, 1991.
- ❑ Recognition of ASME's accreditation program only applies to programmatic aspects of the Quality Assurance (QA) programs and ASME Code items.
- ❑ Does not apply to non-Code items that may be supplied by ASME's accredited suppliers such as N-type Certificate Holders (CH), Quality System Certificate (QSC) Holders, or Qualified Material Organizations (QMOs)



# Background

4

- Supplement 2 of Information Notice 86-21 also clarified that purchasers of certain ASME Code items may use another method to verify that the ASME Code accredited suppliers are effectively implementing their QA programs.
- Specifically, implementation audits may not be necessary for procuring items that are:
  - ▣ Relatively simple and standard in design, manufacturing, and testing.
  - ▣ Adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery.



# Regulations

5

- Criterion IV, “Procurement Document Control,” of Appendix B to 10 CFR Part 50 states, in part, that:
  - ▣ “Measures shall be established to assure that applicable *regulatory requirements*, design bases, and other requirements which are necessary *to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services*, whether purchased by the applicant or by its contractors or subcontractors.”



# Regulations

6

- Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50 states, in part, that:
  - “Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, *conform to the procurement documents*. These measures shall include provisions, as appropriate, for source evaluation and selection, *objective evidence of quality furnished by the contractor or subcontractor*, inspection at the contractor or subcontractor source, and examination of products upon delivery.”



# Regulations

7

- 10 CFR Part 21.31, “Procurement Documents,” states:
  - ▣ “Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part *shall ensure that each procurement document for a facility, or a basic component issued by him, her or it* on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply.”
- Reminder: ASME Section III Code pressure retaining components are *basic components (i.e., safety-related)*



# What Does It All Mean?!?!?!?

8







# Procurement Requirements

9

- When buying a basic component (i.e., safety-related) from an ASME accredited supplier such as an N-type CH, QSC Holder, or a QMO, must Appendix B to 10 CFR Part 50 and 10 CFR Part 21 be imposed on the procurement documents?
- When buying a basic component from an N-type CH, or a QSC Holder, or a QMO, Appendix B to 10 CFR Part 50 and 10 CFR Part 21 *shall* be imposed on the procurement documents.



# Procurement Requirements

10

- Why is this important?
  - ▣ Ensures that adequate QA is applied throughout the manufacturing process.
  - ▣ Ensures that Appendix B to 10 CFR Part 50 and 10 CFR Part 21 are adequately passed down to the sub-suppliers.
- Reminder: Relieving a sub-supplier providing a basic component of their responsibilities under 10 CFR Part 21 is not appropriate.



# Auditing Requirements

11

- If the NRC recognizes the ASME accreditation programs as evidence of having a documented QA program that meets the requirements of Appendix B to 10 CFR Part 50, am I required to audit these type of suppliers?
  - ▣ Yes, the NRC's recognition of the ASME accreditation programs only applies to the programmatic aspects of the QA programs. Suppliers still need to ensure that their sub-suppliers are effectively implementing their approved QA programs.
- Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction), Revision 5, endorses NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," with certain conditions.
- NQA-1-2015 is incorporated into Subsection NCA of ASME Section III.



# Auditing Requirements

12

- However, implementation audits may not be necessary for procuring items that are:
  - ▣ Relatively simple and standard in design, manufacturing, and testing;
  - ▣ Adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery.
- Use of this exception should be evaluated and documented.



# Auditing Requirements

13

- If a vendor procures ASME Section III Code material from an non-audited N-type CH or QSC, can the material be classified as a basic component?
  
- ▣ If the vendor issuing the purchase order did not perform a QA implementation audit of the N-type CH or QSC, and decides to perform testing of the material upon receiving it, then the material is not considered a basic component until testing is performed. On the other hand, if the vendor had performed a QA implementation audit, then the material would already be considered a basic component.



# Summary

14

- Imposing Appendix B and 10 CFR Part 21 in the procurement documents:
  - ▣ Ensures that adequate QA is applied throughout the manufacturing process.
  - ▣ Ensures that both of these regulatory requirements are passed down to the sub-suppliers.
  - ▣ Provides reasonable assurance that basic components will perform their intended safety function.
  - ▣ Provides a method for licensees and the NRC to be notified of any problems that could potentially render a component inoperable and create a substantial safety hazard.



# Summary

15

- Recognition of the ASME accreditation program applies only to the programmatic aspects of the QA programs - audits are required to verify adequate implementation.
- Recognition is not applicable for non-Code items that may be supplied by N-type CHs, QSC Holders, or MOs.
- Audits are not required for items meeting the exceptions listed in Supplement 2 of IN 86-21.



# Questions

16

## □ Contact Information

- Yamir Diaz-Castillo  
Mail Stop O-4A17M  
Washington, DC 20555-0001  
Phone: 301-415-2228  
Email: [yamir.diaz-castillo@nrc.gov](mailto:yamir.diaz-castillo@nrc.gov)

